Development and Evaluation of the PROWL Questionnaire

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Special Thanks
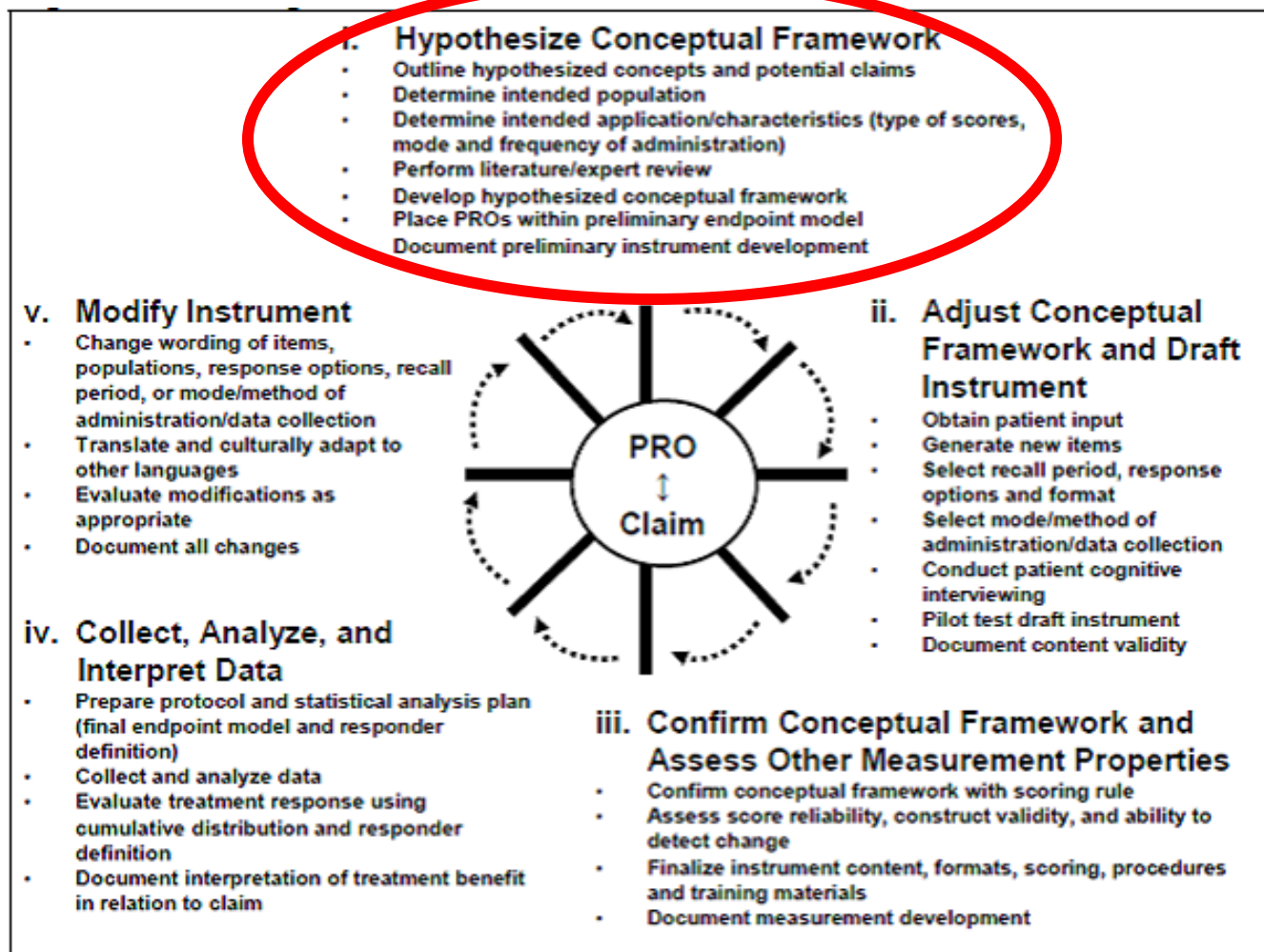
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Patient-Reported Outcomes (PROs)

- "Any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else"

  » Patient reports about their health

  - What they can do and how they feel

  » Patient evaluations of health care

PRO Iterative Development Process

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v. Modify Instrument
- Change wording of items, populations, response options, recall period, or mode/method of administration/data collection
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- Evaluate modifications as appropriate
- Document all changes

ii. Adjust Conceptual Framework and Draft Instrument
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PRO ↕ Claim

iii. Confirm Conceptual Framework and Assess Other Measurement Properties
- Confirm conceptual framework with scoring rule
- Assess score reliability, construct validity, and ability to detect change
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- Document measurement development

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM205269.pdf
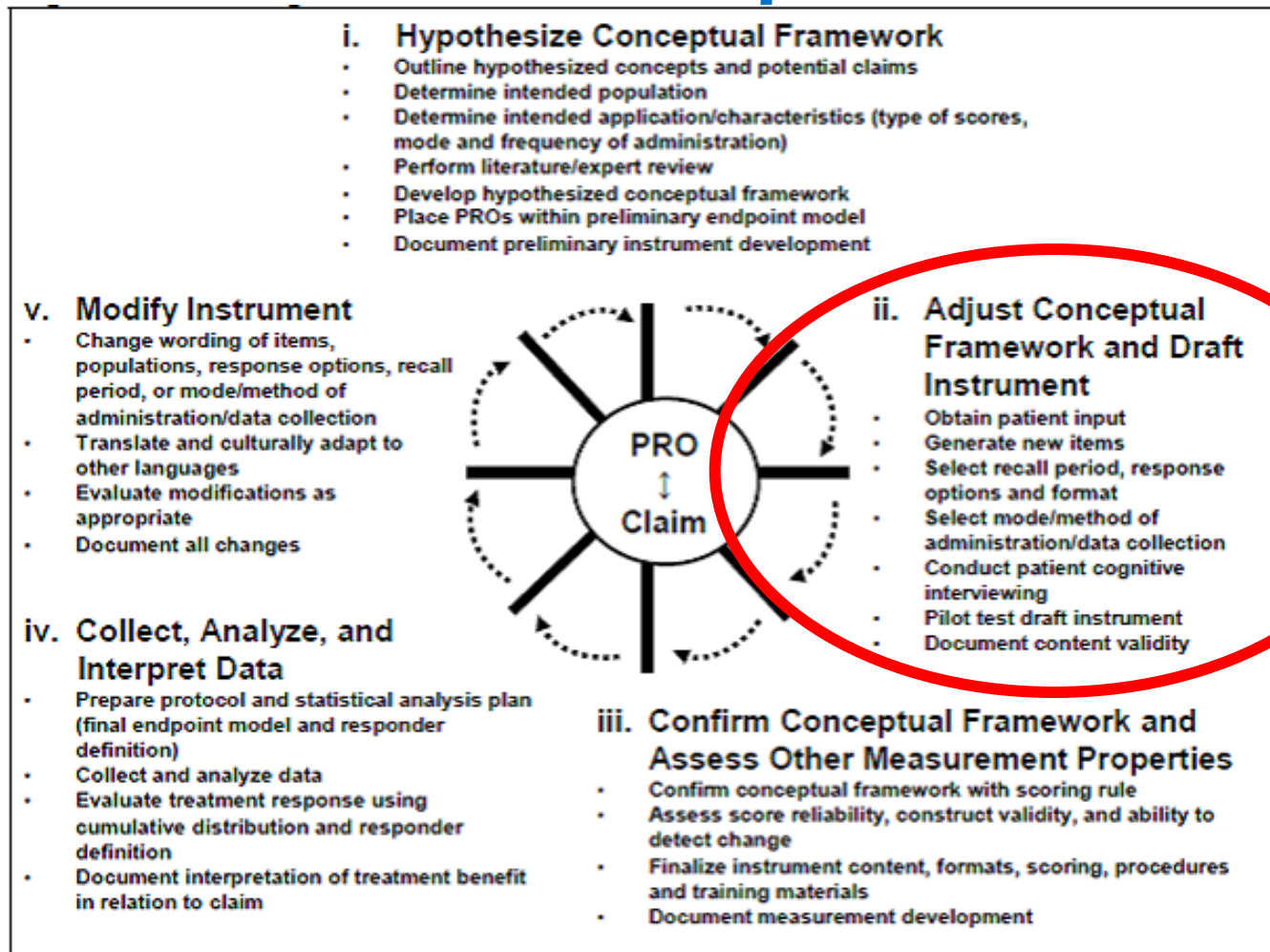
4

Identify Concepts and Hypothesize Conceptual Framework

- Literature, media, and citizen reports used to identify concepts of interest and potential confounders

  » Functioning limitations

  » Satisfaction with surgery

  » Dry eye symptoms

  » Expectations of surgery

  » Coping

  » Optimism/pessimism

  » Depression/anxiety symptoms

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6

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Adjust Conceptual Framework and Draft Instrument

- Evaluated published surveys of target concepts

- Obtained permission to use copyrighted items

- Wrote new items

Included Several Existing Measures in Draft Instrument

- National Eye Institute Refractive Error Quality of Life (NEI-RQL-42)
- National Eye Institute Visual Functioning Questionnaire (VFQ-25)
- Ocular Surface Disease Index (OSDI)
- Life Orientation Test Revised (LOT-R)
- Brien Holden Vision Institute Multidimensional Quality of Life (BHVI QOL) Scale for Myopia
- Work Productivity Activity and Impairment (WPAI)
- Patient Health Questionnaire (PHQ-4)
- Marlowe-Crowne Socially Desirable Response Set

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Example of Visual Symptom Aberration Item

INSTRUCTIONS: The next few questions are about _starbursts_. By starbursts, we mean _seeing rays of light_ coming out from lighted objects, such as in the car headlights in the images below. These images may not represent exactly what you see and your symptoms may be more or less severe than what is shown.

No starbursts ⟶ **Severe starbursts**

In the last 7 days, have you seen any **starbursts**?

1. Yes, but ONLY when NOT wearing glasses or contact lenses
2. Yes, but ONLY when wearing glasses or contact lenses
3. Yes, when wearing AND when not wearing glasses or contact lenses
4. No, not at all

9

Cognitive Interviews to Evaluate Draft Instrument

- Objectives:

  » To evaluate the content and ordering of the questionnaire, coverage of treatment-related issues pertinent to LASIK patients

  » To evaluate the usability of the electronic format of the questionnaire

Cognitive Interviews Conducted by RAND

- Conducted in Los Angeles, CA and Washington, DC
- Pre-operative patients (n=9)
  » Adults very likely to have LASIK in the next 6 months
- Post-operative patients (n=9)
  » 1 dissatisfied
  » 4 satisfied
  » 4 with visual symptoms
- General Exclusions
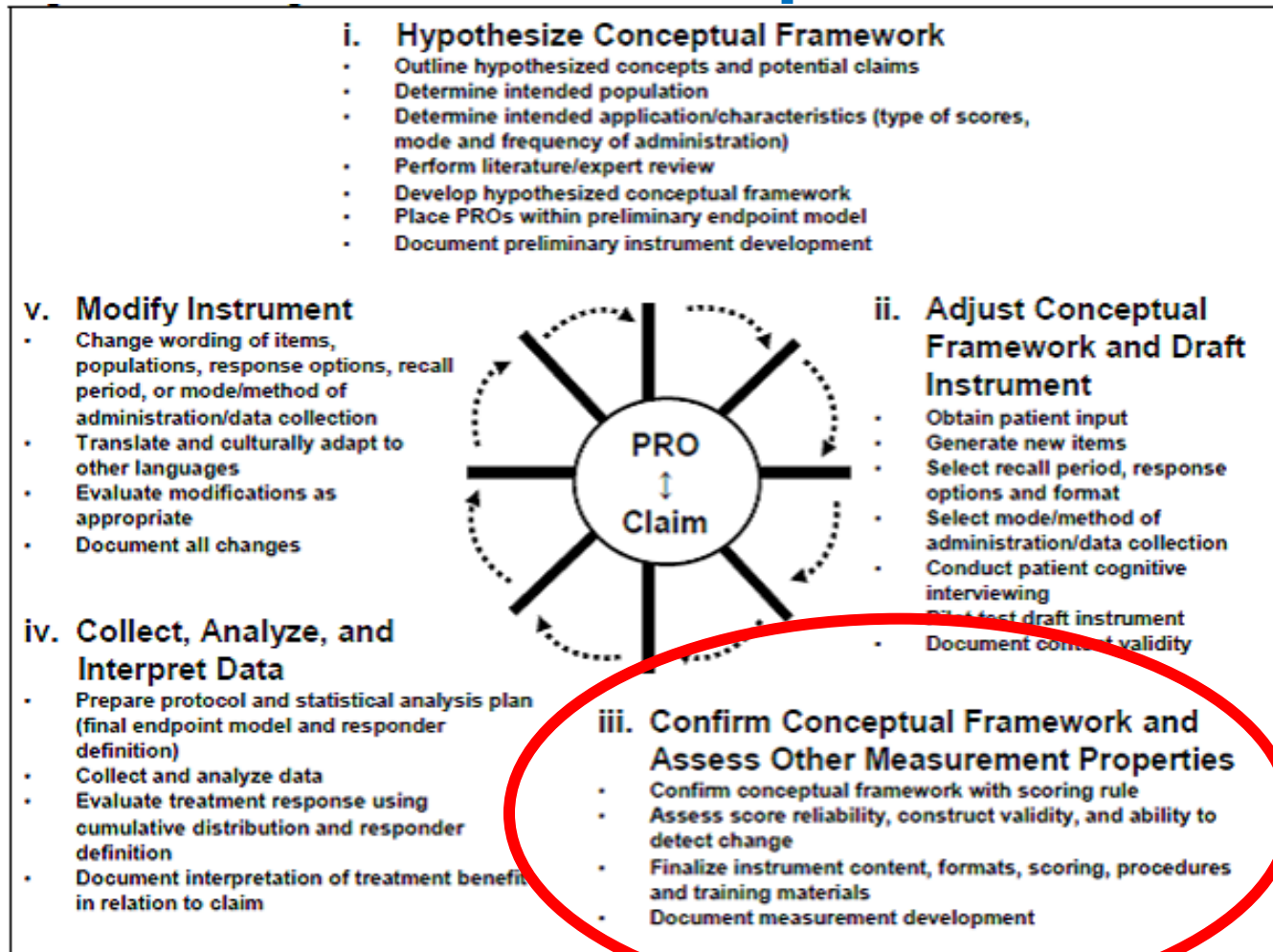 » Eye care professionals, web site designers, and prior refractive surgery

Adjust Conceptual Framework: Implementing Cognitive Interview Results

- Modified questionnaire with the following changes
  - » Ordering of items
  - » Clearer wording of some items
  - » Additional phrases to remind respondents of time frame
  - » Instructions were shortened and bulleted
  - » Formatting of web-based questionnaire to resemble other online surveys

Survey Measures

- Existing Measures
  - » 7 NEI-RQL-42 scales (23 of 42 items)
  - » NEI-VFQ-25 driving scale (3 items)
  - » 2 of 3 Ocular Surface Disease Index scales (8 of 12 items)
  - » Lost work and productivity due to eye problems (3 items)
- New Measures
  - » Visual aberrations (4 scales)
  - » Expectations of spectacle independence/vision clarity (6 items)
  - » Satisfaction with vision (1 item)
  - » Satisfaction with LASIK surgery (8 items)
- Optimism (10 items)
- Health Proneness (10 items)
- Depression and Anxiety (4 items)

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14

Assess Measurement Properties: Reliability

Degree to which the same score is obtained when the *target* or thing being measured (person, plant or whatever) has not changed.

✓Internal consistency (items)

   ✓Need 2 or more items

✓Test-retest (administrations) correlations

   ✓Need 2 or more time points

Internal Consistency Reliability and Item-Scale Correlations for 23 Multi-Item Scales

- PROWL-1
  - » Median alpha = 0.78 (range: 0.55-0.98)
- PROWL-2
  - » Median alpha = 0.81 (range: 0.63-0.97)
- Item-scale correlations (hypothesized scales vs other scales) support item discrimination across scales

Reliability Estimates for Visual Symptoms & Functioning

Domain	Coefficient alpha		Test-retest correlation	
	PROWL1	PROWL 2	PROWL1	PROWL 2
Visual Aberrations				
Glare	0.98	0.97	0.62	0.66
Starbursts	0.97	0.97	0.82	0.63
Halos	0.97	0.97	0.73	0.72
Double Image/Ghosting	0.96	0.95	0.54	0.86
NEI-RQL-42				
Clarity of vision	0.67	0.71	0.80	0.77
Near vision	0.74	0.76	0.61	0.85
Far vision	0.79	0.78	0.79	0.93
Glare	0.55	0.65	0.48	0.69
Diurnal vision	0.89	0.86	0.77	0.74
Activity Limitations	0.76	0.71	0.80	0.90
OSDI	0.69	0.78	0.76	0.88

17

Reliability Estimates for Psychological Factors

Domain	Coefficient alpha		Test-retest correlation	
	PROWL1	PROWL 2	PROWL1	PROWL 2
NEI-RQL-42 Worry	0.83	0.82	0.68	0.69
Health Proneness	0.85	0.84	0.70	0.79
Optimism	0.77	0.81	0.70	0.91
Depression/Anxiety	0.80	0.81	0.68	0.85
Expectations of spectacle independence/vision clarity	0.61	0.63	0.75	0.85

PROWL-1 Item-Scale Correlations Example

Item Number	Ocular Surface Disease	NEI-RQL Clarity Vision
Q65 (eyes sensitive to light)	0.38*	-.28
Q66 (eyes feel gritty)	0.32*	-.20
Q67 (painful or sore eyes)	0.32*	-.15
Q68 (blurred vision)	0.46*	-.57
Q69 (poor vision)	0.47*	-.53
Q70 (uncomfortable—wind)	0.44*	-.15
Q71 (uncomfortable—humidity)	0.45*	-.15
Q72 (uncomfortable—air cond.)	0.31*	-.15
Q5 (how clear is your vision?)	-.21	0.12*
Q34a (distorted vision)	-.35	0.52*
Q35a (blurry vision)	-.45	0.65*
Q36a (trouble seeing)	-.48	0.62*

Assess Measurement Properties: Validity

- Content validity: Does measure "appear" to reflect what it is intended to (expert judges or patient judgments)?

  » Do items operationalize concept?

  » Do items cover all aspects of concept?

  » Does scale name represent item content?

- Construct validity

  » Are the associations of the measure with other variables consistent with hypotheses?

Threats to Validity

- Those with higher levels of expectations about surgery will be less satisfied with surgery

  » The correlations between expectations and satisfaction with surgery were <u>not</u> statistically significant at the 1-month, 3-month, and 6-month follow-ups in PROWL-1.

Threats to Validity

- Those with lower health proneness at baseline will be less satisfied with surgery

  » Only the correlation of health proneness with 3-month satisfaction with surgery was statistically significant and it was a small correlation ($r = 0.14$, $p = 0.0443$) in PROWL-1.

Threats to Validity

- Those with depressive/anxiety symptoms at baseline will be less satisfied with surgery

  » Only the correlation of the PHQ-4 with 6-month satisfaction with surgery was statistically significant and it was a small correlation ($r = -0.19$, $p = 0.0043$), PROWL-1.

23

Support for Validity

- Those with a greater degree of visual aberrations will be less satisfied with surgery

    » Correlations statistically significant in hypothesized direction at 1-month, 3-month and 6-month follow-up in PROWL-1:
        - Glare (r's = 0.34, 0.36, 0.43)
        - Starbursts (r's = 0.27, 0.24, 0. 32)
        - Haloes (r's = 0.37, 0.34, 0.49)
        - Double images (r's = 0.43, 0.37, 0.39)

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Usability Results

	PROWL-1	PROWL-2
Minutes to Complete (median)	25	20
Length of Questionnaire		
About right	46%	64%
A little too long	40%	33%
No problems using computer		
True	86%	90%
False	10%	8%
Ease of taking questionnaire by computer vs paper		
Easier	54%	69%
Harder	14%	5%

Summary

- This study provides support for use of PROWL questionnaire

  » Reliable

  » Measures the concepts it purports to measure

  » Practical to administer even in a mobile population

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